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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,569	04/18/2005	Klas Norrby	4864-108 US	2433

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EXAMINER	
XIE, XIAOZHEN	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
08/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/505,569	NORRBY, KLAS	
	Examiner	Art Unit	
	XIAOZHEN XIE	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 June 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *33-40 and 47-54*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646

Continuation of 5. Applicant's reply has overcome the following rejection(s): 112-1 rejections as being lack of written description and enablement; and 112-2 rejections as being indefinite.

Continuation of 11. does NOT place the application in condition for allowance because:

The amended and newly added claims 33-40, 47-52 and 54 remain rejected under 35 U.S.C. 102(e), as being anticipated by Miller et al. (U. S. Patent No: 6,426,362 B1), for reasons set forth previously.
Applicant argues that Miller et al. teaches a method of treating the disruption of energy metabolism or ameliorating injury secondary to stress, which requires administering a composition of tocopherol along with a synergistic agent, in which the synergistic agent may be a human apo-lactoferrin. Applicant argues that Miller et al. teaches that if the synergistic agent is administered individually, it is ineffective for the intended therapeutic purpose (Example 8). Applicant argues that the instant invention includes a limitation of administering a therapeutically effective amount of human apo-lactoferrin, which is defined in the specification as relating to an amount that will "lead to the desired therapeutic effect, i.e. an amount that will enhance the VEGF mediated angiogenesis." and that Miller et al. does not describe a therapeutically effective amount of apo-lactoferrin that will enhance VEGF mediated angiogenesis. Applicant argues that Miller et al. fails to disclose any of the additional limitations disclosed in claim 35. Applicant further argues that human lactoferricin is not disclosed by Miller et al.
Applicant's arguments have been fully considered but have not been found to be persuasive.
First, Miller et al. teaches the use of a composition comprising tocopherol and lactoferrin, e.g., human apo-lactoferrin, for ameliorating disruption of energy metabolism secondary to stress, e.g., hypoxia stress.
Second, in Example 8 wherein the synergistic agent (bovine lactoferrin) when administered individually, was relative ineffective, the experiment used bovine lactoferrin, instead of human apo-lactoferrin. These two proteins have different properties. Further, the combination of tocopherol and bovine lactoferrin was effective as shown in the example. It is noted that the instant claims employ the phrase "comprising".
Third, MIller et al. teaches the amount of the composition can be 0.1 to about 1000 mg per kg body weight per day (col. 27 line 64 bridging col. 28, line 24), and the ratio of tocopherol:lactofferin can be, for example, 1:1. While the specification defines the therapeutically effective amount as that "lead to the desired therapeutic effect, i.e. an amount that will enhance the VEGF mediated angiogenesis.", no dosage ranges are described. However, the amount used in the working examples, 20 mg/kg twice daily, falls within the range taught in the Miller et al.
Fourth, Miller et al. teaches treating ischemic disorders, such as stroke, which anticipates the limitations disclosed in claim 35.
Finally, Miller et al. teaches lactoferricin in col. 16, lines 13-47, (incorporated by reference).

The amended and newly added claims 33-40, 42-44 and 47-54 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hiroki et al. (JP 09-194388), in view of Clement (Acta Chir. Belg., 2000, 100(5):190-193), for reasons set forth previously.
Applicant argues that the computer-generated translation from the Japanese language is grammatically unreadable. Applicant's argument is persuasive,
Attached please find the official translation of the Japanese patent translated by the USPTO Translation Branch.